K010033

RICHARD WOLF
Medical Instruments Corporation

JAN 1 0 2002

353 Corporate Woods Parkway
Vernon Hills, IL 60061
Phone: 847-913-1113
Customer Service: 800-323-WOLF
www.richard-wolf.com

510(k) Summary of Safety and Effectiveness

Submitter:			**Date of Preparation:** January 3,2001
Company / Institution name: RICHARD WOLF MEDICAL INSTRUMENTS CORP.			**FDA establishment registration number:** 14 184 79
Division name (if applicable): N.A.			**Phone number (include area code):** (847) 913-1113
Street address: 353 Corporate Woods Parkway			**FAX number (include area code):** (847) 913-0924
City: Vernon Hills	**State/Province:** Illinois	**Country:** USA	**ZIP / Postal Code:** 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			
Product Information:			
Trade name: Light Projector, ENDOCAM LIGHT		**Model number:** 4251.007 5551.107/.961/..901	
Common name: Light Projector and Endoscopic Camera		**Classification name:** Light Source, Endoscopic and Camera, Television, Endoscopic	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 pre-enactment	1 Light source 4008, 4046, 4246	1 Richard Wolf
2 K950502	2 CCD Endocam Office 5501	2 Richard Wolf
3 K944821 K952696	3 Light source, Xenon	3 Richard Wolf
4 K982965	4 CCD Endocam Office 5502/5507 CF	4 Richard Wolf

1.0 Description

The Light Projector LP 4251 is a light source with two 250W Halogen reflector lamps with lamp change button and connection for endoscope.

In the Endocam Light 5551 an endoscopic 1 CCD camera is added.

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2.0 Intended Use

The Light Projector LP 4251 provides light for examination, diagnostic and therapeutic applications, particularly in endoscopy.

The ENDOCAM LIGHT 5551 dual-purpose device is designed for illumination and video endoscopy of natural and artifically created body cavities in diagnostic and therapeutic endoscopy.

3.0 Technological Characteristics

The two lamps of the Light Projector 4251 can be changed easily by a button.

In the Endocam Light 5551, the camera electronics and the lenses with C-mount connection are integrated into the camera head.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k) devices sold by Richard Wolf.

5.0 Performance Data

The electrical devices conform to the international standards IEC60601-1 +A1 +A2, IEC 60601-1-1-1 + A1 and IEC 601-2-18 and to the relevant provisions of the European Device Directive 93/42/EEC. This is confirmed by the CE mark.

6.0 Clinical Tests

Clinical tests were not performed.

7.0 Conclusions Drawn

These devices are designed and tested to assure their safety and effectiveness when used according to the instructions manual.

By: Robert L Casarsa Date: Jan 02, 2001

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 0 2002

Richard Wolf Medical Instruments Corp.
Robert L. Casarsa
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K010033
Trade Name: Light Projector with Endoscopic Camera
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: October 23, 2001
Received: October 24, 2001

Dear Mr. Casarsa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

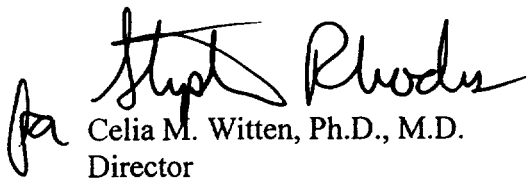
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K010033

Device Name: Light Source with Endoscopic 1CCD Camera

Intended Use:

The Light Projector LP 4251 provides light for examination, diagnostic and therapeutic applications, particularly in endoscopy.

The ENDOCAM LIGHT 5551 dual-purpose device is designed for illuminating and video endoscopy of natural and artificially created body cavities in diagnostic and therapeutic endoscopy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010033

Prescription Use ✓
Per 21 CFR 801.109

OR

Over-The Counter